IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: **Stamm et al**

Application No. **10/665,520** Group Art Unit: **1615**

Filed: **September 22, 2003** Examiner: **Sheikh**

For: **Processes For Producing Fenofibrate Compositions**

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Information Disclosure Statement

Pursuant to 37 CFR §§ 1.56, 1.97 and 1.98, Applicants bring to the attention of the Examiner the documents listed on the attached PTO-1449 Form. A copy of the Non Patent Literature Documents and the Foreign Patent Documents is attached hereto.

Applicants direct the Examiner's attention to:

(a) Cite No. 1 on PTO-1449 Form No. 1 of 9, the dissolution profile on page 12 at Table VII in Laboratoires Fournier's undated document entitled "Fenofibrate Tablets 54-160 MG Dissolution Test Conditions Development Studies, Dissolution Test Specification Recommendations."

(b) Cite No. 24 on PTO-1449 Form 3 of 9, the Declaration under 37 CFR § 1.132 by Phillippe Reginault filed in US Application No. 10/288,425 on March 7, 2005.

(c) On PTO-1449 Form 5 of 9, the Declaration under 37 CFR § 1.132 by Pascale Blouquin with attached Exhibits 1-5 filed in US Application No. 09/899,026 on March 7, 2005; Laboratoires Fournier's Lab Notebook No. 1 from 18 February 1997 to 15 May 1997; Laboratoires Fournier's Lab Notebook No. 2 from 16 May 1997 to 30 July 1997.

(d) *In re TriCor Indirect Purchaser Antitrust Litigation*, District of Delaware, Civil Action No. 05-360.

(e) *CVS Pharmacy, Inc. et al. v. Abbott Laboratories et al*, District of Delaware, 1:05-cv-00605-KAJ.

(f) *Walgreen Co. et al v. Abbott Laboratories et al*, District of Delaware, 1:05-cv-00404-KAJ.

(g) *Pacificare Health Systems, Inc. v. Abbott Laboratories et al*, District of Delaware, 1:05-cv-00591-KAJ.

(h) *Painters District Council No. 30 Health and Welfare Fund et al v. Abbott Laboratories et al*, District of Delaware, 1:05-cv-00360-KAJ.

(i) *Louisiana Wholesale Drug Company, Inc. v. Abbott Laboratories et al*, District of Delaware, 1:05-cv-00340-KAJ;

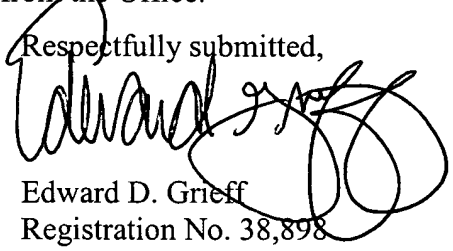
(j) *Paul T. Tegan v. Abbott Laboratories et al*, Central District of California, 2:05-cv-05410-GAF-AJW.

The submission of this Information Disclosure Statement does not represent that a search has been made and does not constitute an admission that the listed documents, oppositions and/or litigations are material to patentability or that the listed documents are prior art.

This Information Disclosure Statement is being filed after the mailing date of a first office action on the merits, but before a final office action or a notice of allowance. Accordingly, the Commissioner is authorized to charge the fee of **$180** to Deposit Account No. 22-0261. The Commissioner is authorized to charge any other necessary fees or credit any overpayments to Deposit Account No. 22-0261.

Applicants respectfully request that the PTO return an initialed copy of the PTO-1449 Form with the next communication from the Office.

Respectfully submitted,



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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 9

Complete if Known	
Application Number	10/665,520
Filing Date	September 22, 2003
First Named Inventor	Stamm
Art Unit	1615
Examiner Name	Sheikh
Attorney Docket Number	224616

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	1	Laboratoires Fournier undated document entitled "Fenofibrate Tablets 54-160 mg Dissolution Test Conditions Development Studies, Dissolution Test Specification Recommendations"	
	2	"Second Amended Answer, Affirmative Defenses, and Counterclaims" filed by Teva on 7-29-2005 in Abbott Laboratories et al v. Teva Pharmaceuticals USA, Inc. DE, CA No. 02-1512.	
	3	"First Amended Counterclaims" filed by Impax on 9-23-2005 in Abbott Laboratories et al v. Impax Laboratories, Inc., Delaware, CA No. 03-120-KAJ.	
	4	"Amended Complaint" filed by CVS Pharmacy et al on 9-23-2005 in In Re TriCor Direct Purchaser Antitrust Litigation, Delaware, CA No. 05-340.	
	5	"Amended Complaint" filed by Walgreen Co. et al on 9-23-2005 in In Re TriCor Direct Purchaser Antitrust Litigation, Delaware, CA No. 05-340.	
	6	"Amended Complaint" filed by Painters' District Council No. 30 et al on 9-23-2005 in In Re TriCor Direct Purchaser Antitrust Litigation, Delaware, CA No. 05-340.	
	7	"Amended Complaint" filed by Louisiana Wholesale Drug Co. et al on 10-3-2005 in In Re TriCor Direct Purchaser Antitrust Litigation, Delaware, CA No. 05-340.	
	8	"Defendant's Responses to Plaintiffs Interrogatories" filed by Impax on 8-6-2003 in Abbott Laboratories et al v. Impax Laboratories, Inc., Delaware, CA No. 03-120-KAJ.	
	9	"Amended Answer" filed by Impax on 1-4-2005 in Abbott Laboratories et al v. Impax Laboratories, Inc., Delaware, CA No. 03-120-KAJ.	
	10	"Reply Memorandum" filed by Impax on 2-25-2005 in Abbott Laboratories et al v. Impax Laboratories, Inc., Delaware, CA No. 03-120-KAJ.	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

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	11	"Memorandum Opinion" by District Judge Jordan dated 5-6-2005 in Abbott Laboratories et al v. Impax Laboratories, Inc., Delaware, CA No. 03-120-KAJ.	
	12	"Opening Brief in Support of Motion for Summary Judgment" by Teva filed on 12-23-2004 in Abbott Laboratories et al v. Teva Pharmaceuticals USA, Inc., Delaware, CA No. 02-1512.	
	13	"Opening Brief in Support of Motion for Summary Judgment" by Teva filed on 12-10-2004 in Abbott Laboratories et al v. Teva Pharmaceuticals USA, Inc., Delaware, CA No. 02-1512.	
	14	"Memorandum Opinion" by District Judge Jordan dated 5-6-2005 in Abbott Laboratories et al v. Teva Pharmaceuticals USA, Inc., Delaware, CA No. 02-1512.	
	15	Opposition to European Patent No. 1 273 293 filed 9-2-2005 by Ethypharm (French Language Docuement).	
	16	Opposition to Israel Patent No. 130790 filed 5-4-2005 by Teva; and Remarks in Response to Oppostion filed on 9-23-2005 (English language translations).	✓
	17	Munoz et al, Atherosclerosis, 110(Suppl.):S45-S48 (1994).	
	18	Pharmaceutical Pelletization Technology, Marcel Dekker, Inc., Volume 37, pages 1-13; 160-161; and 234-235 (1989).	
	19	Modern Pharmaceutics, Third Edition, Marcel Dekker, Inc., apges 131-133 and 335-356 (1996).	
	20	Pharmaceutical Dosage Forms, Tablets, Second Edition, Marcel Dekker, Inc., pages 5-28; 88-107; 133; 142; 160-165; and 260-267 (1989).	

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	21	Shepherd Atherosclerosis, 110(Suppl.)S55-S63 (1994).	
	22	Adkins et al, Drugs, 54(4):615-633 (October 1997).	
	23	Letter from Teva/Novopharm to Fournier Pharma Inc. regarding Invalidity and Ambiguity of Canadian Patent Nos. 2,219,475 and 2,372,576 (pages 1-15)(September 19, 2005).	
	24	Declaration under 37 CFR 1.132 by Phillippe Reginault filed in US Application No. 10/288,425 on March 7, 2005.	
	25	Pharmaceutical Pelletization Technology, Ghebre-Sallassie, Ed., Marcel Dekker, Inc., New York, Chapters 7 and 10 (1989).	
	26	Handbook of Pharmaceutical Excipients, 2nd Ed., pages 48-87, 141-144, 229-232, 252-261, 280-282, 392-401, 424-427, 448-450, 462-469, 491-493 (1994).	
	27	Remington's Pharmaceutical Sciences, 18th Ed., pages 1633-1665 (1985).	
	28	European Pharmacopoeia, 3rd Ed., pages xiii-xvii and 127-131 (1996).	
	29	The United States Pharmacopoeia, Vol. 23, pages liv-lvi, 1791-1793, 1924-1938 (1994).	
	30	CRC Handbook of Chemistry & Physics, 73rd Ed., Chapter 15, page 32 (1992).	

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Attorney Docket Number	224616

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	31	Suzuki et al, Chem. Pharm. Bull., 49(4):373-378 (2001).	
	32	Shah et al, International Journal of Pharmaceutics, 125:99-106 (1995).	
	33	Giunchedi et al, International Journal of Pharmaceutics, 130:41-47 (1996).	
	34	Sangalli et al, Boll. Chim. Farmaceutico, 128(7-8):242-247 (1989).	
	35	Kuchiki et al, "Stable Solid Dispersion System Against Humidity," Yakuzaigaku, 44(1):31-37 (1984).	
	36	Guichard et al, "A New Formulation of Fenofibrate: Suprabioavailable Tablets," Current Medical Research and Opinion, 16(2):134-138 (2000).	
	37	Boullay, "Microgrinding and Dissolution," S.T.P. Pharma, 1(4):296-299 (1985). (French-language document and English language translation).	✓
	38	International Dictionary of Medicine and Biology, Volume 2, page 1774, John Wiley & Sons, Inc. (1986).	
	39	Opposition to EP 952 829 by Winthrop Arzneimitel GmbH filed March 31, 2005.	
	40	Opposition to EP 952 829 by Laboratoires SMB SA filed April 11, 2005.	

Examiner Signature		Date Considered	

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Sheet 5 of 9

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	41	Papers filed on April 15, 2005, by Ethypharm in Response to Patent Proprietor's Statement of Opposition to EP 952 829.	
	42	Opposition to EP 0 952 829 by Ethypharm filed December 11, 2003.	✓
	43	Handbook of Pharmaceutical Excipients, Second Edition, pages 392-399 (1994).	
	44	Complaint, US District Court for the District of Delaware, Civil Action No. 04-350, Reliant Pharmaceuticals v. Abbott Laboratories et al (June 1, 2004).	
		Declaration under 37 CFR 1.132 by Pascale Bloquin filed in US Application No. 09/899,026 on March 7, 2005.	
		Laboratoires Fournier's Lab Notebook No. 1 (attached as Exhibit 1 (French) and Exhibit 3 (English translation) to the 132 Declaration by Bloquin).	✓
		Laboratoires Fournier's Lab Notebook No. 2 (attaches as Exhibit 2 (French) and Exhibit 4 (English translation) to the 132 Declaration by Bloquin).	✓

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U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US- 6,027,747	02-22-2000	Terracol et al	
		US- 5,633,015	05-27-1997	Gillis et al	
		US- 5,145,684	09-08-1992	Liversidge et al	
		US- 4,629,624	12-16-1986	Grouiller et al	
		US- 4,344,934	08-17-1982	Martin et al	
		US- 2005/0032878 A1	02-10-2005	Deboeck et al	
		US- 4,961,890	10-09-1990	Boyer	
		US- 6,159,499	12-12-2000	Seth	
		US- 6,207,198	03-27-2001	Seth	
		US- 6,248,355	06-19-2001	Seth	
		US- 4,795,643	01-03-1989	Seth	
		US- 5,824,341	10-20-1998	Seth et al	
		US- 6,096,341	08-01-2000	Seth	
		US- 6,033,686	03-07-2000	Seth	
		US- 6,048,547	04-11-2000	Seth et al	
		US- 6,117,453	09-12-2000	Seth et al	
		US- 6,348,469	02-19-2002	Seth	
		US- 4,463,743	03-13-1984	Schonafinger et al	
		US- 4,716,033	12-29-1987	Denick, Jr.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
		CA 2,142,848	03-17-1994	Janssen Pharmaceuticals		
		CA 960,670	01-07-1975	Orchimed SA		
		WO 98/31360	07-23-1998	Pharma Pass		
		WO 97/12581	04-10-1997	Pharma Pass		
		CA 2,219,475	07-09-2002	Laboratoires Fournier		
		CA 2,372,576	02-10-2004	Laboratoires Fournier		

Examiner Signature		Date Considered	

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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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		US- 4,588,058	12-10-1985	Schonafinger et al	
		US- 4,957,746	09-18-1990	Valducci	
		US- 4,806,361	02-21-1989	Harrison et al	
		US- 4,820,521	04-11-1989	Panoz et al	
		US- 4,663,150	05-05-1987	Panoz et al	
		US- 2,953,497	09-20-1960	Press	
		US- 4,524,060	06-18-1985	Mughal et al	
		US- 4,721,709	01-26-1988	Seth et al	
		US- 5,073,379	12-17-1991	Klimesch et al	
		US- 4,684,516	08-1987	Bhutani	
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		WO 96/21439	07-18-1996	Galephar PR Inc.		
		WO 03/013500	02-20-2003	Laboratoires SMB SA		
		EP 0 012 523	06-25-1980	American Home Products		
		WO 97/12580	04-10-1997	Pharma Pass		
		EP 0 179 583	04-30-1986	Merck & Co.		
		EP 0 193 958	09-10-1986	PPG Industries, Inc.		

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		WO 96/04892	02-22-1996	Pharma Pass		
		WO 98/31361	07-23-1998	Stamm et al		
		WO 96/01621	01-25-1996	Stubberud et al		
		WO 82/01649	05-27-1982	Laruelle		
		EP 0 952 829	03-05-2003	Stamm et al		
		EP 0 761 208	03-12-1997	Duclos et al		

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PTO/SB/08A (07-05)
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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 9 of 9

Complete if Known	
Application Number	10/665,520
Filing Date	September 22, 2003
First Named Inventor	Stamm
Art Unit	1615
Examiner Name	Sheikh
Attorney Docket Number	224616

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-			
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
		EP 0 122 077	10-17-1984	Elan Corp.		
		EP 0 164 959	12-18-1985	Sterwin AG		
		EP 0 168 360	01-15-1986	Valducci		
		EP 0 239 541	09-30-1987	Warner-Lambert Co.		
		EP 0 256 933	02-24-1988	Ethypharm		

Examiner Signature		Date Considered	

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IDW

PTO/SB/17 (12-04v2)
Approved for use through 7/31/2006. OMB 0651-0032
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Effective on 12/08/2004.
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL
For FY 2006

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 180.00

Complete if Known	
Application Number	10/665,520
Filing Date	September 22, 2003
First Named Inventor	Stamm
Examiner Name	Sheikh
Art Unit	1615
Attorney Docket No.	31672-224616

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____

☒ Deposit Account Deposit Account Number: 22-0261 Deposit Account Name: Venable LLP

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, **except for the filing fee**

☒ Charge any additional fee(s) or underpayment of fee(s) under 37 CFR 1.16 and 1.17 ☒ Credit any overpayments

FEE CALCULATION (All the fees below are due upon filing or may be subject to a surcharge.)

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

	FILING FEES		SEARCH FEES		EXAMINATION FEES		
Application Type	**Fee ($)**	**Small Entity Fee ($)**	**Fee ($)**	**Small Entity Fee ($)**	**Fee ($)**	**Small Entity Fee ($)**	**Fees Paid ($)**
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	Fee ($)	Small Entity Fee ($)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180

Total Claims		Extra Claims	Fee ($)		Fee Paid ($)
_____	- 20 or HP =	_____	x _____	=	_____

HP = highest number of total claims paid for, if greater than 20.

Multiple Dependent Claims	
Fee ($)	**Fee Paid ($)**
_____	_____

Indep. Claims		Extra Claims	Fee ($)		Fee Paid ($)
_____	- 3 or HP =	_____	x _____	=	_____

HP = highest number of total claims paid for, if greater than 3.

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets		Extra Sheets		Number of each additional 50 or fraction thereof		Fee ($)		Fee Paid ($)
_____	- 100 =	_____	/50	_____	(round up to a whole number) x	_____	=	_____

4. OTHER FEE(S)

	Fees Paid ($)
Non-English Specification, $130 fee (no small entity discount)	
Other (e.g., late filing surcharge): X **Information Disclosure Statement fee**	**$180.00**

SUBMITTED BY			
Signature		Registration No. (Attorney/Agent) 38,898	Telephone
Name (Print/Type)	Edward D. Grieff		Date May 9, 2006